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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,221	07/27/2006	Alvin Janski	060905.00001	6469

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EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
10/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,221	JANSKI ET AL.	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *6-11,14,15 and 18* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☒ Claim(s) *9-11* is/are allowed.

7)☒ Claim(s) *6-8,14,15 and 18* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *27 July 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. According to the Amendment, filed 29 July 2011, the status of the claims is as follows:

Claims 6, 9, 14, 15, and 18 are currently amended;

Claims 7 and 11 are as originally filed;

Claims 8 and 10 are previously presented; and

Claims 1-5, 12, 13, 16, and 17 are cancelled.

2. The rejection to claims 6-11 under 35 U.S.C. 101 as being directed to non-statutory subject matter is WITHDRAWN in view of the Amendment, filed 29 July 2011.

3. The rejection to claims 1, 4, and 5 under 35 U.S.C. 101 as being directed to non-statutory subject matter is rendered moot in view of the Amendment, filed 29 July 2011, cancelling these claims.

4. The rejection to claims 1, 4, 5, and 13 under 35 U.S.C. 101 as being directed to non-statutory subject matter is rendered moot in view of the Amendment, filed 29 July 2011, cancelling these claims.

Response to Arguments

5. As stated in the Applicant's Remarks, filed 29 July 2011, dependent claim 15 was previously indicated as allowable in the prior Office Action, and has been rewritten in the Amendment, filed 29 July 2011, into independent form to include all of the limitations of

claim 13. In addition, dependent claims 14 and 18 have been amended to depend from claim 15. Claims 6-11 were previously indicated as allowable in the prior Office Action.

However, the indicated allowability of claims 6-8, 14, 15, and 18 is withdrawn in view of the newly discovered reference(s). Rejections based on the newly cited reference(s) follow.

Drawings

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the feature "comparing the measured concentration levels with a predetermined profile indicative of an onset of at least one sickle-cell pathology" in claim 6, and "comparing the measured concentration levels with a predetermined profile indicative of an onset of at least one selected (NO)-related negative influence; and wherein said at least one selected (NO)-related negative influence is associated with an ivHb-dependent decrease in (NO) bioavailability" in claim 9, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

7. Claims 8-11 are objected to because of the following informalities: claims 8-11 contain the phrase “(NO)” which makes it unclear whether the letters in the parenthesis is part of the claim or not. Examiner suggests amending this phrase in each occurrence with "nitric oxide" to make the claim clearer as to the meaning of the phrase. Appropriate correction is required.

8. Claim 9 is objected to because of the following informalities: claim 9 contains the phrase “ivHb” which is an undefined abbreviation. Examiner suggests amending this phrase with "intravascular hemoglobin" to make the claim clearer as to the meaning of the phrase. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 6-8, 14, 15, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Braun et al, U.S. Patent No. 7,101,340 B1 ("Braun").

As to Claim 6, Braun teaches the following:

A method for predicting the onset of one or more sickle-cell anemia related pathologies in a human patient having sickle-cell anemia (i.e. "***This invention relates generally to a medical device and protocols for using such a device to facilitate diagnosis of medical conditions in patients based on breath analysis profiles obtained using highly sensitive laser spectroscopies, for example Cavity Ring-down (CRD) spectroscopy, and photoacoustic (PA) spectroscopy.***", see col. 1, ll. 12-17; and see figs. 1, 2A, and 2B), said method comprising:

providing an electronic device ("***analyzer***") 100 (i.e. "***The use of the breath analyzer 100…***", see col. 8, l. 36; and see fig. 1);

measuring a concentration level of at least one breath gas exhaled by the patient over a period of time (i.e. "***Variations over time in the concentration of the gas of interest may be independent of variations over time in flow 205 of exhaled breath 255***.", see col. 5, ll. 57-59); and

comparing the said measured concentration levels with a predetermined concentration profile indicative of an onset of at least one sickle-cell pathology (i.e. "***The analyzer 100 then compares the spectroscopic breath profile for a patient to a database of spectroscopic profiles characteristic of one or more medical conditions to facilitate diagnosis for the presence or absence of a medical condition. Computer 124 alerts the user to a "match" or "nonmatch" in patient versus database spectroscopic profiles. Such information is then interpreted by a physician or other health care professional to facilitate diagnosis of the presence or absence of a medical condition.***", see col. 8, ll. 42-53; wherein the pathology is "infection" such as "***pneumonia***" and "***heliobactor pylori***", see col. 2, ll. 56-60, and col. 7, ll. 18-22),

wherein said step of comparing is carried out by the electronic device 100 (i.e. "***The analyzer 100 then compares the spectroscopic breath profile for a patient to a database of spectroscopic profiles characteristic of one or more medical conditions to facilitate diagnosis for the presence or absence of a medical condition.***", see col. 8, ll. 42-45).

As to Claim 7, Braun teaches the following:

wherein said sickle-cell anemia pathologies include one or more pathologies from a set of pathologies including pain, anemia, stroke, or infection (the pathology is "infection" such as "***pneumonia***" and "***heliobactor pylori***", see col. 2, ll. 56-60, and col. 7, ll. 18-22).

As to Claim 8, Braun teaches the following:

wherein each of said one or more selected sickle-cell anemia related pathologies are each influenced by a decreased nitric oxide (NO) bioavailability (i.e. "***In another particular embodiment, a medical device for analyzing gases in expired breath for facilitating diagnosis of a medical condition is configured to analyze gases in expired breath such as ammonia, nitric oxide…***", see col. 2, ll. 61-64; and i.e. "***Recently, researchers have shown that the chemical composition of expired breath can be an accurate, timely, and painless indicator of the health of an individual. See Phillips, M. et al., J. Chromatography (1999), B729, 75, hereby incorporated by reference herein. For example, a number of exhaled gases such as ammonia, nitric oxide, aldehydes and ketones have been associated with kidney and liver malfunction, asthma, diabetes, cancer, and ulcers. (Alving, K et al., Eur. Respir. J. (1993), 6, 1368; Paredi, P. et al., Chest (1999), 116, 1007; and Atherton, J., Gut (1994), 35, 723.)***", see col. 1, ll. 31-36).

As to Claim 15, Braun teaches the following:

An apparatus for predicting the onset of a medical condition in a human patient (i.e. "***This invention relates generally to a medical device and protocols for using such a device to facilitate diagnosis of medical conditions in patients based on***

breath analysis profiles obtained using highly sensitive laser spectroscopies, for example Cavity Ring-down (CRD) spectroscopy, and photoacoustic (PA) spectroscopy.", see col. 1, ll. 12-17; and see figs. 1, 2A, and 2B), comprising:

means ("***detector***") 108 for measuring a plurality of concentration levels of at least one breath gas exhaled by the patient (i.e. "***Variations over time in the concentration of the gas of interest may be independent of variations over time in flow 205 of exhaled breath 255***.", see col. 5, ll. 57-59; and see col. 4, ll. 42-54);

means ("***analyzer***") 100 for comparing said measured concentration levels with at least one predetermined concentration profile indicative of an onset of the medical condition (i.e. "***The analyzer 100 then compares the spectroscopic breath profile for a patient to a database of spectroscopic profiles characteristic of one or more medical conditions to facilitate diagnosis for the presence or absence of a medical condition. Computer 124 alerts the user to a "match" or "nonmatch" in patient versus database spectroscopic profiles. Such information is then interpreted by a physician or other health care professional to facilitate diagnosis of the presence or absence of a medical condition.***", see col. 8, ll. 42-53),

wherein the medical condition is selected from a set of medical conditions including pain and the occurrence of stroke (i.e. "***In another embodiment a medical device for analyzing gases in expired breath for facilitating diagnosis of a medical condition utilizes a database of spectroscopic breath analysis profiles is stored within the memory component for medical conditions including kidney malfunction, liver malfunction, asthma, diabetes, cancer, ulcer, schizophrenia,***

neurological disorders, pneumonia, halitosis, alcohol ingestion, and organ trauma.", see col. 2, ll. 53-60); and

a display operatively coupled to said means for comparing (i.e. "***The data resulting from the analysis could then be transferred to and stored in computer 124, which may further have an input device or devices, such as a keyboard or mouse, an output device such as a video monitor, printer, or other means of displaying data, memory, and an appropriate CPU.***", see col. 4, ll. 55-60);

wherein said means 100 for comparing is further configured to generate a profile responsive to said measured concentration levels, said profile representative of a likelihood of onset for the said medical condition (i.e. "***The analyzer 100 then compares the spectroscopic breath profile for a patient to a database of spectroscopic profiles characteristic of one or more medical conditions to facilitate diagnosis for the presence or absence of a medical condition. Computer 124 alerts the user to a "match" or "nonmatch" in patient versus database spectroscopic profiles. Such information is then interpreted by a physician or other health care professional to facilitate diagnosis of the presence or absence of a medical condition.***", see col. 8, ll. 42-53); and

wherein said means 100 for comparing is further configured to control said display to display said profile (i.e. "***The data resulting from the analysis could then be transferred to and stored in computer 124, which may further have an input device or devices, such as a keyboard or mouse, an output device such as a***

video monitor, printer, or other means of displaying data, memory, and an appropriate CPU.", see col. 4, ll. 55-60).

As to Claim 14, Braun teaches the following:

wherein said means 100 for comparing includes a logic circuit ("PC Computer") 124 (see fig. 1).

As to Claim 18, Braun teaches the following:

wherein said means 108 for measuring is configured to measure a concentration of carbon monoxide breath gas exhaled by the patient (i.e. "***In another particular embodiment, a medical device for analyzing gases in expired breath for facilitating diagnosis of a medical condition is configured to analyze gases in expired breath such as ammonia, nitric oxide, ketones, methane, ethane, butane, pentane, carbon dioxide...***", see col. 2, ll. 61-65).

Allowable Subject Matter

10. Claims 9-11 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter:

As to Claims 9-11, the prior art of record does not teach the method for predicting the onset of at least one (NO)-related negative influence in a human patient, including: comparing the said measured concentration levels with a predetermined concentration profile indicative of an onset of at least one selected (NO)-related negative influence; and wherein said at least one selected (NO)-related negative

influence is associated with an ivHb-dependent decrease in (NO) bioavailability, wherein said step of comparing is carried out by the electronic device.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/
Primary Examiner, Art Unit 3735
10/18/2011